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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,198	01/20/2000	Shigeaki Kato	06501-054001	5541

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EXAMINER
MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
1646	23

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/489,198	KATO ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 12-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Formal Matters

Claims 8-11 were amended in Paper No. 22, 5/8/2003. Claims 1-27 are pending. Claims 1-7, 12-27 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 8-11 are under consideration.

Response to Amendment

The rejection of claims 8-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claims 8 and 9 under 35 U.S.C. 102(b) as being anticipated by WO 9621677 (Moore et al.) have been obviated by Applicant's amendment and are thus withdrawn.

The rejection of claims 8-11 under 35 U.S.C. 103(a) as being unpatentable over WO 9621677 (Moore et al.) have been obviated by Applicant's amendment and are thus withdrawn.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for screening for a nucleic acid which encodes a polypeptide that converts an inactive form of vitamin D3 into an active form, does not reasonably provide enablement for a method for screening for a gene encoding a polypeptide that converts an inactive form of vitamin D3 to an active form, or a method for screening for a gene encoding an

polypeptide that converts a ligand precursor into a ligand. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.

In the instant case, claims 8-9 are drawn to methods of screening for genes that encode a polypeptide that converts any and all ligand precursors from any and all animals into an active form, while claims 10-11 are drawn to a method for screening for a gene encoding a polypeptide that converts an inactive form of vitamin D3 to an active form. The specification discloses methods of screening for a nucleic acid which encodes a polypeptide that converts an inactive form of vitamin D3 into an active form wherein the nucleic acid is from human or mouse (i.e. SEQ ID NO: 1, 2 see page 16), while the claims encompass methods of screening for genes which encode a polypeptide which converts any and all ligand precursors from any and all animals into an active form. Applicant has provided insufficient guidance to enable one of ordinary skill in the art to screen for genes from any and all animals encoding a protein that can convert any and all inactive ligands to active form. Although the specification outlines procedures for screening for nucleic acids that encode polypeptides that convert inactive vitamin D3 to active, to attempt to extrapolate this screening assay to encompass any and all nuclear receptors and any and all ligands is merely an invitation to the artisan to use the current invention as a starting point for further experimentation.

Firstly, since detailed information regarding the structural and functional requirements of the gene encoding the polypeptide, and since the term "gene" encompasses elements that are not

particularly described or enabled by extrapolation, e.g. promoters, enhancers, untranslated regions and introns, it is unpredictable as to which genes, if any, meet the limitations of the claims are enabled. Applicant is required to enable one of skill in the art to make and use the claimed invention, while the claims encompass methods using genes that the specification only teaches one skilled in the art to test for functional variants to be used in the claimed method.

Secondly, it would require undue experimentation for one of skill in the art to practice the broadly claimed method, since the skilled artisan would have to first make or select sequences as likely candidates without any direction or guidance regarding which sequences would likely have an effect. This is because there is no guidance set forth regarding the nature of the precursor ligand, nor do the claims set forth the function that the active ligand must possess, i.e. it is not clear what ligands and precursors, other than vitamin D3 precursor are functional in this assay nor what properties of vitamin D3 are to be extrapolated to facilitate selection of any other ligands. Thus, due to the large quantity of experimentation necessary to generate the infinite number of sequences and ligand precursors recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Given the breadth of claims 8-11 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to practice the claimed invention.

Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

These are genus claims. Claims 8-9 are drawn to methods of screening for genes that encode a polypeptide that converts any and all ligand precursors from any and all animals into an active form, and claims 10-11 are drawn to a method for screening for a gene encoding a polypeptide that converts an inactive form of vitamin D3 to an active form. The specification discloses methods of screening for a nucleic acid which encodes a polypeptide that converts an inactive form of vitamin D3 into an active form wherein the nucleic acid is from human or mouse (i.e. SEQ ID NO: 1, 2 see page 16). However, detailed information regarding the structural and functional requirements of the gene encoding the polypeptide, as well as structural and functional requirements of the encoded polypeptide itself are lacking, because the claims do

not set forth the nature of the precursor ligand, nor do the claims set forth the function that the active ligand must possess, and also since the term "gene" encompasses elements that are not particularly described, e.g. promoters, enhancers, untranslated regions and introns the specification and claim do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
September 23, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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